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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/869,079

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Stefan Leo Jozef Masure

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7899

7590

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,079

Applicant(s)

MASURE ET AL.

Examiner

Scott D. Priebe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 16-21, 23-27, 30-35 and 38-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12, 16-21, 23-27, 30-35 and 38-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 9-12, 16 (in part directed to nucleic acid molecule), 17-18 (in part directed to transgenic cell), and 40, drawn to a nucleic acid molecule (including expression vector) that expresses human Akt-3 protein, cell comprising same, and method of using the cell in a method for producing a pharmaceutical formulation comprising compound that binds Akt-3 protein.

Group II, claim(s) 5 and 38-39 (in part directed to antisense molecule of claim 5), drawn to an antisense molecule that hybridizes with a nucleic acid molecule that expresses human Akt-3 protein, and a method of using same for treatment of disease.

Group III, claim(s) 6-8, 16 (in part directed to protein), 19, 30-32, 41, and 42, drawn to human Akt-3 protein, and the first recited method of using same in an acellular assay for identifying compounds that influence activity of human Akt-3 protein comprising introducing a test compound into a reaction mixture comprising human Akt-3 protein, a substrate of the protein, and a phosphate source. .

Group IV, claim(s) 17-18 (in part directed to tissue or multi-cellular organism), drawn to a multicellular transgenic organism comprising a transgene that expresses human Akt-3 protein, and tissue obtained therefrom (excluding isolated cells).

Group V, claim(s) 20, 21, 23, 24, and 38-39 (in part directed to antibody of claim 21), drawn to an antibody that binds to human Akt-3 protein, and a method of using same for treatment of disease.

Group VI, claim(s) 25 and 27, drawn to a cell-based assay for identifying inhibitors of human Akt-3 protein comprising treating cells, which are transformed with an expression vector "activating the Akt-3 pathway" and had been cultured in the presence of a survival factor, with a candidate compound after removal of the survival factor, and a compound identified thereby.

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Group VII, claim(s) 26 and 43, drawn to a cell-based assay for identifying inhibitors of human Akt-3 protein activity comprising treating cells, which are transformed with an expression vector “activating the Akt-3 pathway,” with a candidate compound in the presence of a death factor, and a compound identified thereby.

Group VIII, claim(s) 33-35, drawn to an acellular assay for identifying agents that influence activity of human Akt-3 protein comprising introducing a test compound into a reaction mixture comprising a PH domain of human Akt-3 protein and a phospholipid, and an agent identified thereby.

Group IX, claim(s) 38-39 (in part directed to inhibitors of claim 27), drawn to a compound that inhibits human Akt-3 protein activity, and a method of using same for treatment of disease. (The second recited method of using the compound of claim 27).

Group X, claim(s) 38-39 (in part directed to an agent of claim 35), drawn to a method for treatment of disease with an agent that affects the binding of a phospholipid to the PH domain of human Akt-3 protein. (The second recited method of using the agent of claim 35.)

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

37 CFR 1.475(b) states:

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

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If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

37 CFR 1.475(d) also states:

If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

37 CFR 1.475(e) further states:

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.

In view of 37 CFR 1.475 (b)-(e), Group I is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

Groups I-VIII are directed to a nucleic acid encoding human Akt-3 (and cells comprising such nucleic acid), and antisense molecule that inhibits expression of human Akt-3, human Akt-3 protein, a transgenic multicellular organism (or tissue therefrom) comprising a transgene that expresses human Akt-3, an antibody that binds human Akt-3 protein, a compound that inhibits human Akt-3 activity upon removal of a survival factor, a compound that inhibits human Akt-3 activity when in the presence of a death factor, and an agent that affects binding of the PH domain of human Akt-3 protein to a phospholipid, respectively, and the first recited method of using each. Each of these are structurally and functionally different products, and each has different uses. The special technical feature of each of these inventions resides in the specific product to which each is directed. In the case of inventions VI, VII, and IX, the screening assay is a method of using the compound or agent, not a method of making the compound or agent, i.e.

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the screening assay uses compounds that are already made. The methods of each invention cannot be practiced with the product of the others. As a result, these inventions do not share the same technical feature, or special technical feature.

The methods of inventions IX and X are second methods of using the compound of invention VI and the agent of invention VIII, respectively. As per 37 CFR 1.475(b), multiple methods of using the same product are not deemed to share unity of invention with the product and first recited method of use.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER